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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,786	07/25/2006	David Deperthes	KZI-003US	4550

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EXAMINER

LEE, JAE W

ART UNIT PAPER NUMBER

1656

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/552,786

Applicant(s)

DEPERTHES ET AL.

Examiner

Jae W. Lee

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,9,10,12-22,28-34 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 6,9,10,12-22,28-34 and 36-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Application status

Claims 6, 9, 10, 12-22, 28-34, 36-45 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 6, 9, 10, 17, 28-34, 36, 38-43, drawn to a recombinant inhibitor protein of a kallikrein comprising a serpin sequence wherein, the Reactive Serpin Loop (RSL) of said serpin sequence is modified by at least one substrate active site sequence, fragments thereof, a molecular chimera thereof, a combination thereof, and variants thereof, specific for said kallikrein, and a diagnostic kit for the detection of a kallikrein in a specimen comprising the recombinant inhibitor protein of claim 39.

Group II, claim(s) 12-16, 37, 44 and 45, drawn to an isolated DNA sequence encoding the recombinant inhibitor protein of claim 39, and a diagnostic kit for the detection of a kallikrein in a specimen comprising DNA sequence selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 9, 11, 13, a sequence complementary thereof, fragment thereof, and variants thereof.

Group III, claim(s) 18-22, drawn to a method of treating or preventing a proteolysis-associated disorder in a mammal comprising administering to said mammal the pharmaceutical composition of claim 17.

For Group I above, further restrictions are also required under 35 USC 121.

Therefore, election is required of one of Groups I-II and one of (A)-(E).

- (A) MD820
- (B) MD62
- (C) MD61
- (D) MD67
- (E) MDCI

Because this application contains claims directed to patentably distinct species, in addition to the above restrictions, please elect a single serpin sequence as listed in claim 9 if the Applicants elect Group I from above restriction requirement.

In addition to the above restrictions, please elect a single SEQ ID NO if the Applicants elect Group I from above restriction requirement. This application contains claims directed to the following patentably distinct species: SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21 or SEQ ID NO: 22.

In addition to the above restrictions, please elect a single SEQ ID NO if the Applicants elect Group II from above restriction requirement. This application contains claims directed to the following patentably distinct species: SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 9, SEQ ID NO: 11 or SEQ ID NO: 13.

The species are independent or distinct because these serpin sequences and SEQ ID NOs represent structurally different nucleic acid and amino acid sequences.

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Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

These claims will be examined to the extent they read upon the elected species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6, 9, 10, 12-22, 28-34, 36-45 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression

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"special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Chao et al. (J. Lab. Clin. Med., 1996, 127(6): 612-620) teach a recombinant Kallistatin, a novel human tissue kallikrein inhibitor which has high degree of sequence identity with other human serpins, and biochemical characterization of the Kallistatin, which corresponds to the limitation of claim 39, in the recitation of "a recombinant inhibitor protein of a kallikrein comprising a serpin sequence wherein, the Reactive Serpin Loop (RSL) of said serpin sequence is modified by at least one substrate active site sequence, fragments thereof, a molecular chimera thereof, a combination thereof, and variants thereof, specific for said kallikrein", and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

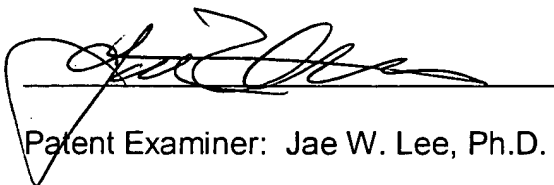
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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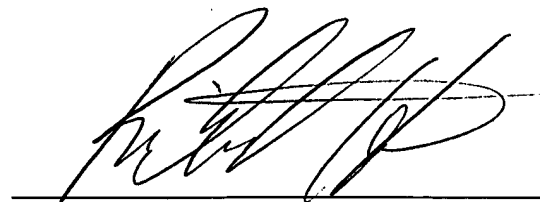
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Patent Examiner: Jae W. Lee, Ph.D.



**RICHARD HUTSON, PH.D.
PRIMARY EXAMINER**